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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,725	10/19/2004	Toshiro Omori	042872	2520

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EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,725	OMORI ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *8-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 July 2007 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1-29 are currently pending.

The election/restriction requirement inadvertently mailed out on 09/24/2007 has been withdrawn. However, the original election/restriction requirement mailed out on 04/14/2006 still stands.

Claims 8-26 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 May 2006.

Claims 1-7 and newly added claims 27-29 are currently under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A composition obtained from barley shochu stillage.

Claim Objections

Claims 1, 28 and 29 is objected to because of the following informalities: please remove "of" from between the percent and the amino acid or sugar. For example, in line 5, delete "of" from between "by weight" and "glutamic acid". Please make this correction throughout the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a culture medium, does not reasonably provide enablement for a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight

of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and wherein the composition is capable of treating the onset of alcoholic hepatopathy in a patient in need thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claim 27 is drawn to a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to

10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and wherein the composition is capable of treating the onset of alcoholic hepatopathy in a patient in need thereof.

The nature of the invention is complex in that claim 27 is drawn to a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said

polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and wherein the composition is capable of treating the onset of alcoholic hepatopathy in a patient in need thereof. The composition is not enabled for treatment of the onset of alcoholic hepatopathy in a patient in need thereof.

Breadth of the Claims: The claim is broad in that the claim recites a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley

shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and wherein the composition is capable of treating the onset of alcoholic hepatopathy in a patient in need thereof. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes a composition comprising an unadsorbed fraction, wherein said unabsorbed fraction is formed by subjecting a barley shochu stillage: obtained by the production of shochu from a barley as a raw material: to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unabsorbed product of said separation treatment is said unabsorbed fraction, in which wherein the unadsorbed fraction contains plural peptides having an average chain length of from 3.0 to 5.0, and these peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10% by weight of aspartic acid, from 4 to 9% by weight of proline and from 4 to 8% by weight of serine on the basis of the total weight of the amino acids forming said peptides (See pages 10 and 11). The specification further describes a method of determining the effect of feeding freeze-dried powder of liquid fraction (A) of barley shochu stillage on rats (See “Experiment 1”, pages 12-16), wherein

the specification concludes that the foregoing results have revealed that the freeze-dried powder (A') of the liquid fraction (A) of the barley shochu stillage is not suggestive of the actual use as a drug for positively inhibiting the onset of alcoholic hepatopathy. The specification further describes a method of determining the effect of feeding a desorbed fraction obtained by subjecting the liquid fraction of the barley shochu fraction to a separation treatment by adsorption using a synthetic adsorbant and eluting the resulting adsorbed fraction with an alkali on rats (See "Experiment 2", pages 16-19), wherein the specification concludes that the foregoing results have revealed that the freeze-dried powder (B') of the desorbed fraction (B) of the barley shochu stillage has slightly shown a tendency of inhibiting induction of the alcoholic hyerlipemia, but not shown a tendency of inhibiting induction of the alcoholic fatty liver and alcoholic hepatitis and that the desorbed fraction is substantially free from the activity of inhibiting the onset of alcoholic hepatopathy. The specification further describes a method of determining the effect of feeding a fraction formed by subjecting the liquid fraction of the barley shochu stillage to a separation treatment by adsorption using a synthetic adsorbant (C) on rats (See "Experiment 3", pages 19-22), wherein the specification concludes that the freeze-dried powder (C') of the unadsorbed fraction (C) has the marked activity of inhibiting the onset of alcoholic hepatopathy. The specification further describes other methods involving various fractions of barley shochu stillage, wherein the various fractions are tested on rats, which have inconclusive results with respect to the inhibition of alcoholic hepatopathy (See "Experiment 5" and "Experiment 6"

(pages 23-33). Nowhere in the specification are *in vitro* or *in vivo* examples provided that show healing of alcoholic hepatopathy.

The specification envisions that by administering a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and that the compostion will have utility in humans by treating the onset of alcoholic hepatopathy.

However, no working examples are provided with regard to a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24

to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and wherein the composition is capable of treating the onset of alcoholic hepatopathy.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Diehl (U, "Alcoholic liver disease". Clin Liver Dis, Vol. 2, No. 1 (February 1998) 103-118, Abstract only) teaches that effective therapies for most individuals with alcoholic liver disease have not been found and that the high per capita consumption of alcohol, coupled with the dearth of effective treatments and the failure of most affected individuals to abstain from alcohol, explains the difficulty in treatment.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a composition comprising plural peptides having an average chain length of from 3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition and wherein the composition is capable of treating the onset of alcoholic hepatopathy.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to use to a composition comprising plural peptides having an average chain length of from

3.0 to 5.0, free saccharides and polysaccharides, wherein: said plural peptides comprise from 24 to 38 % by weight of glutamic acid, from 4 to 20 % by weight of glycine, from 5 to 10 % by weight of aspartic acid, from 4 to 9 % by weight of proline and from 4 to 8 % by weight of serine on the basis of the total weight of amino acids forming said peptides, and said free saccharides have a saccharide composition comprising from 2 to 6% by weight of glucose, from 0.5 to 5% by weight of xylose and from 0.5 to 3% by weight of arabinose, and said polysaccharides have a saccharide composition comprising from 6 to 16% by weight of glucose, from 3 to 12% by weight of xylose and from 0.5 to 4% by weight of arabinose, wherein said composition is formed by subjecting barley shochu stillage, obtained by the production of shochu from barley *(Hordeum vulgar* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claim 27 is not considered to be fully enabled by the instant specification.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the free amino acids" and “the amino acids in said peptides” in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

Claims 1-7 and newly added claims 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Omori et al. (N, JP 2000-125777 A, Translation provided herein). (Please note that claim 27 has been omitted because Applicant is not enabled for the limitation of claim 27).

Omori teaches a method of obtaining a composition by subjecting residual liquid by-produced in the shochu-production using barley as a raw material and obtained by distilling the shochu to a solid-liquid separation to provide a liquid component, filtering the obtained liquid component to provide a clear liquid, concentrating the obtained clear liquid to provide a concentrated liquid, subjecting the concentrated liquid to absorption treatment by using a synthetic absorbent to provide an unabsorbed (non-adsorbed) fraction, and drying the obtained unabsorbed (non-adsorbed) fraction (See abstract and paragraph 0001). Omori teaches that the synthetic absorbent can be an aromatic system synthetic material or a methacrylic synthetic adsorbent material (See claim 5).

Omori further teaches that freeze drying is a suitable method of drying the non-adsorbed fraction (See paragraph 0014).

Although Omori does not teach that the composition obtained by solid/liquid separation of shochu stillage contains the components claimed by Applicant nor does Omori teach that the composition is a pharmaceutical nor does Omori teach that the composition obtained is capable of treating the onset of alcoholic hepatopathy in a patient in need thereof; however, the method of making the composition taught Omori is one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the composition obtained by solid/liquid separation of shochu stillage taught by Omori, which recites the same method steps as claimed by Applicant to provide a product-by-process, inherently contains the components in the ranges claimed by Applicant, is inherently a pharmaceutical composition.

Therefore, the reference anticipates the claimed subject matter.

Response to Amendment

The declaration under 37 CFR 1.132 filed 01/07/2008 is sufficient to overcome the rejection of claims 1-4 based upon Omori reference (O*) and the rejection of claims 1-7 based upon Omori reference (O*), in view of Kaneuchi et al. (P*).

Response to Arguments

Claim Rejections - 35 USC § 112

Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground of rejection.

Claim Rejections - 35 USC § 102

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 07/02/2007 and 01/07/2008, with respect to the rejection of claims 1-4 under 35 U.S.C. 102(a) as being anticipated by Omori et al. (O*) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection of claims 1-7 and newly added claims 28 and 29 under 35 U.S.C. 102(b) as being anticipated by Omori et al. (N, JP 2000-125777 A, Translation provided herein).

Claim Rejections - 35 USC § 103

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 07/02/2007 and 01/07/2008, with respect to the rejection of claims 1-7 based upon Omori reference (O*), in view of Kaneuchi et al. (P*) have been fully considered and are persuasive. The rejection of claims 1-7 based upon Omori reference (O*), in view of Kaneuchi et al. (P*) has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Amy L. Clark
March 18, 2008

/Michele Flood/
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